

Message Text

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ACTION HEW-01

INFO OCT-01 EA-07 ISO-00 SCI-03 CU-03 CIAE-00 INR-10

NSAE-00 RSC-01 DRC-01 /027 W
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P 091014Z OCT 74

FM AMEMBASSY TOKYO

TO SECSTATE WASHDC PRIORITY 5169

UNCLAS TOKYO 13234

DEPT PASS TO FDA FOR RANDOLPH

E.O. 11652: N/A

TAGS: TPHY, TBIO, JA, US

SUBJECT: US-JAPAN COOPERATIVE ACTIVITIES IN HEALTH: VISIT TO US

REF: A) TOKYO 12800, B) RANDOLPH-MCNEAL TELECON, 10/9

SUMMARY: HERewith LIST OF GOJ DELEGATION AND MORE DETAILED
DRAFT AGENDA. ACTION REQUESTED: REPLY ON ARRANGEMENTS POSSIBLE
FOR FIELD TRIPS HERE REQUESTED FOR OCTOBER 25.

1. ON OCTOBER 9, TSUNASHIMA GAVE EMBOFF FOLLOWING LIST OF
MEMBERS OF GOJ DELEGATION:

A) DR. TAKAJI ISHIMARU (HEAD OF DELEGATION,), DIRECTOR-
GENERAL, ENVIRONMENTAL HEALTH BUREAU, MINISTRY OF HEALTH AND
WELFARE (MHW).

B) MR. MAMORU TSUNASHIMA, HEAD, INTERNATIONAL AFFAIRS
DIVISION, MINISTER'S SECRETARIAT, MHW,

C) MR. HITOSHI YOSHIMURA, HEAD, PLANNING DIVISION, PHARMA-
CEUTICAL AFFAIRS BUREAU, MHW,

D) MR. AKIO ISHII, HEAD, PHARMACEUTICALS AND CHEMICALS
SAFETY DIVISION, PHARMACEUTICAL AFFAIRS BUREAU, MHW,

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E) MR. KAZUTAKA ICHIKAWA, DEPUTY HEAD, FOOD CHEMISTRY

DIVISION, ENVIRONMENTAL HEALTH BUREAU, MHW, AND

F) MR. TAKASHI ICHIKAWA, FIRST SECRETARY, EMBASSY OF JAPAN,
WASHDC.

2. EMBOFF ALSO RECEIVED FOLLOWING MORE DETAILED PROPOSED AGENDA
FROM MHW OFFICIALS:

A. DRUGS

1. CHECK-SYSTEM FOR NEW DRUGS

- (1) STANDARDS FOR EVALUATION OF EFFECTIVENESS AND SAFETY IN
CASE OF LICENSING OF NEW DRUGS.
- (2) FDA'S VIEW ON MUTAGENICITY TEST FOR DRUG LICENSING.

2. SAFETY OF DRUGS

- (1) FOLLOW-UP CHECKS ON SAFETY OF DRUGS INCLUDING THEIR
SIDE-EFFECTS.
- (2) PROGRESS OF DRUG REEVALUATION AND OTHER RELATED PROBLEMS.
- (3) PROBLEMS ON IMPLEMENTATION OF GMP (GOOD MANUFACTURING
PRACTICE).
- (4) BILATERAL CERTIFICATION SYSTEM FOR EXPORT DRUGS
MANUFACTURED THROUGH GMP.

3. KENNEDY COMMITTEE

- (1) FDA'S VIEW ON KENNEDY BILL.
- (2) FUTURE PROSPECTS OF THE COMMITTEE HEARINGS - AGENDA
AND OTHER RELATED BILLS, IF ANY.

4. SUBSTANCE PATENT

- (1) INTRODUCTION OF SUBSTANCE PATENT SYSTEM AND POSSIBLE
REACTIONS OF PHARMACEUTICAL INDUSTRY. (THE IMPACT OF THE
SYSTEM ON ADMINISTRATIVE MANAGEMENT IN THE USA.)

B. FOOD

1. SAFETY OF FOOD ADDITIVES

- (1) PROVISIONAL STANDARDS FOR THE EXAMINATION OF HEREDITARY
SAFETY OF FOOD ADDITIVES AND CONTAMINANTS.
- (2) ON THE INTERIM REPORT BY NIHS (NATIONAL INSTITUTE OF
HYGIENIC SCIENCES): "INDUCTION OF GASTRIC TUMORS IN
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MICE BY FEEDING OF FURYLURAMIDE."

- (3) ON THE REPORT BY DR. Y. IKEDA (NIHS) ON CHRONIC TOXICITY
OF SACCHARIN AND CYCLAMATES.

2. SAFETY OF PLASTIC ADDITIVES FOR APPARATUS, CONTAINERS AND
PACKAGES

- (1) VINYL CHLORIDE MONOMER.
- (2) PHTHALATE ESTERS.

3. ZANDARDS FOR FOOD AND FOOD ADDITIVES

(1) STANDARD-SETTING ACTIVITIES FOR FOOD AND FOOD ADDITIVES TO DATE AND IN FUTURE.

(2) MONITORING OF ACCUMULATION OF TRACE ELEMENTS OF HEAVY METALS AND OTYR CONTAMINANTS IN ANIMALS AND PLANTS.

3. MHW OFFICIAL EXPLAINED THAT GOJ DELEGATION WOULD LIKE TO DIVIDE INTO TWO GROUPS FOR FIELD VISITS ON OCTOBER 25. FIRST GROUP IS YOSHIMURA AND ISHII, TWO OFFICIALS FROM PHARMACEUTICAL AFFAIRS BUREAU. THEY WOULD LIKE TO VISIT FDA'S BUREAU OF DRUGS ON OCTOBER 24 OR AT SOME PRIOR TIME DURING THREE DAYS OF TALKS OCTOBER 21-23. ON OCTOBER 25, AS FIRST PRIORITY, THEY WOULD LIKE TO VISIT PFIZER PLANT IN BROOKLYN TO LEARN HOW GMP IS MAINTAINED IN AN OLDER PLANT, SINCE MANY PLANTS IN JAPAN ARE OLD AND USE OF GMP HERE IS JUST BEGINNING. IF TIME AVAILABLE, AS SECOND PRIORITY THEY WOULD BE HAPPY TO VISIT LAROCHE PLANT IN CLIFTON, NJ, OR ANY OTHER MODERN PLANT FDA MIGHT RECOMMEND.

4. SECOND GROUP IN DELEGATION IS ISHIMARU AND K. ICHIKAWA (BOTH FROM ENVIRONMENTAL HEALTH BUREAU). THEY WOULD LIKE TO VISIT FDA'S BUREAU OF FOODS ON OCTOBER 24 OR AT SOME PRIOR TIME DURING THREE DAYS OF TALKS. ON OCTOBER 25, AS FIRST PRIORITY, THEY WOULD LIKE TO VISIT NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH IN PINE BLUFF, ARKANSAS. AS SECOND PRIORITY, THEY WOULD LIKE TO VISIT A FOOD PLANT WHICH WHAS MODERN EQUIPMENT, PARTICULARLY ONE WHICH PRODUCES "RETORTABLE POUCH FOOD" (A KIND OF DEHYDRATED FOOD).

5. MHW EXPLAINED TAT TSUNASHIMA HIMSELF WILL BE ABLE TO MAKE NEITHER FIELD VISIT, AS HE S SCHEDULED TO LEAVE WASHINGTON FOR MEXICO CITY AT 1400 ON OCTOBER 25. (FYI. TSUNASHIMA INFORMED SCICOUNS HE INVITED TO CUBA TO DISCUSS POSSIBLE GOJ-CUBAN UNCLASSIFIED

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COOPERATION IN HEALTH MATTERS. END FYI.) PLEASE CONTACT T. ICHIKAWA AT JAPANESE EMBASSY TO DETERMINE WHETHER HE WANTS TO ACCOMPANY EITHER GROUP ON FIELD VISITS.

6. MHW WOULD LIKE TO RECEIVE ITINERARY FOR TRAVEL ASAP. THEY ALSO WANT US AGENDA FOR MEETING, BULESS URGENTLY. EMBASSY WOULD APPRECIATE RECEIVING AT LEAST ROUGH ITINERARY BY OCTOBER 11, IF POSSIBLE.

7. EMBASSY COMMENT: NEITHER GROUP IN DELEGATION HAS EXPRESSED INTEREST INVISITING NIH COMPARABLE TO INTEREST IN VISITS HERE REQUESTED. EMBASSY RECOMMENDS MOVING WRAP-UP SESSION TO MORNING OF OCTOBER 24 AS REPLACEMENT AND USING AFTERNOON OF OCTOBER 24 AS TRAVEL TIME, IF NEEDED TO SCHEDULE VISIT TO NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH. END COMMENT.

HODGSON

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Message Attributes

Automatic Decaptioning: X
Capture Date: 01 JAN 1994
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: HEALTH, SCIENTIFIC COOPERATION, ITINERARY, MEETING AGENDA, MINISTERIAL VISITS, MEETING DELEGATIONS
Control Number: n/a
Copy: SINGLE
Draft Date: 09 OCT 1974
Decaption Date: 01 JAN 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Authority: n/a
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 JAN 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1974TOKYO13234
Document Source: CORE
Document Unique ID: 00
Drafter: n/a
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Film Number: D740286-0749
From: TOKYO
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1974/newtext/t19741058/aaaabxot.tel
Line Count: 170
Locator: TEXT ON-LINE, ON MICROFILM
Office: ACTION HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 4
Previous Channel Indicators:
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: A) TOKYO 12800, B) RANDOLPH-MCNEAL T, ELECON, 10/9
Review Action: RELEASED, APPROVED
Review Authority: martinml
Review Comment: n/a
Review Content Flags:
Review Date: 05 MAR 2002
Review Event:
Review Exemptions: n/a
Review History: RELEASED <05 MAR 2002 by chappeld>; APPROVED <05 FEB 2003 by martinml>
Review Markings:

Declassified/Released
US Department of State
EO Systematic Review
30 JUN 2005

Review Media Identifier:
Review Referrals: n/a
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
Secure: OPEN
Status: NATIVE
Subject: US-JAPAN COOPERATIVE ACTIVITIES IN HEALTH: VISIT TO US
TAGS: TPHY, TBIO, JA, US, (TSUNASHIMA, MAMORU), (ISHIMARU, TAKAJI), (YOSHIMURA, HITOSHI), (ISHII, AKIO)
To: STATE
Type: TE
Markings: Declassified/Released US Department of State EO Systematic Review 30 JUN 2005